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REMARKS

Status Summary

The present U.S. patent application is a Divisional of U.S. Patent 6,270,758, filed October 8, 1998. Claims 64-84 are currently pending in the present application.

Claims 64-84 presently stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-4, 6-9, 13-17, 21, 24, 28 and 29 of U.S. Patent 6,270,758. Claims 64-84 also presently stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 64-84 further stand provisionally rejected under 35 U.S.C. § 102 as being anticipated by the references Gao et al. (1995) *Vaccine* 13(9):871-877 (hereinafter referred to as "Gao et al."), Abraham et al. (December 1992) *J. Immunol.* 149:3719-3726 (hereinafter "Abraham et al."), and Elson et al. (1996) "Cholera Toxin as a Mucosal Adjuvant", in Mucosal Vaccines 59-72 (Academic Press) (hereinafter "Elson et al.").

Obviousness-type Double Patenting

The United States Patent and Trademark Office (hereinafter "the Patent Office") has rejected claims 64-84 under the judicially created doctrine of obviousness-type double patenting over claims 1-4, 6-9, 13-17, 21, 24, 28 and 29 of U.S. Patent No. 6,270,758 (hereinafter "the '758 Patent"). According to the Patent Office, the rejected claims and the cited claims are not patentably distinct from each other because "the only difference is that independent claim 1 of the present application is broader in scope than independent claim 1 of the ['758] patent, but there is no reason why the claims of the present application could not have been claimed in the patent." Official Action at page 2.

The Patent Office has stated that a timely filed terminal disclaimer in compliance with 37 CFR § 1.321(c) can be used to overcome an actual or provisional rejection based on a non-statutory double patenting rejection

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provided that the conflicting application is shown to be commonly owned with the present application. Applicants respectfully note that an assignment with respect to the present application and to the '758 patent has been filed and recorded on January 19, 1999 at Reel 9744, Frame 0445, and the assignee is Duke University. Thus, this application and the '758 patent are commonly owned.

In an effort to address the instant rejection, applicants submit herewith a timely filed Terminal Disclaimer in compliance with 37 C.F.R. § 1.321. In submitting the attached Terminal Disclaimer, applicants do not acknowledge that the inventions claimed in the present application and in the '758 Patent are not patentably distinct. Moreover, applicants do not acknowledge that the invention described and claimed in the subject application is an obvious variation of the invention described and claimed in the '758 Patent. Indeed, the Federal Circuit has noted: "[A Terminal Disclaimer] is not an admission of obviousness of the later filed claimed invention in light of the earlier filed disclosure for that is not the basis of the Disclaimer." Quad Environmental Technologies v. Union Sanitary District, 20 U.S.P.Q.2d 1392, 1394 (Fed. Cir. 1991).

The Federal Circuit further noted:

In legal principle, the filing of a Terminal Disclaimer simply serves the statutory function of removing the rejection of double patenting and raises neither presumption nor estoppel on the merits of the rejection. It is improper to convert this simple expedient "obviation" into an admission or acquiescence or estoppel on the merit.

Quad Environmental Technologies, 20 U.S.P.Q.2d at 1394-95.

Therefore, with the submission of the Terminal Disclaimer provided herewith, applicants are simply availing themselves of the statutory function of removing the double patenting rejection. Further, with the submission of the Terminal Disclaimer provided herewith, applicants respectfully request

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withdrawal of the rejection of claims 64-84 under the judicially created doctrine of obviousness-type double patenting over claims 1-4, 6-9, 13-17, 21, 24, 28 and 29 of the '758 Patent.

Claim Rejection - 35 U.S.C. § 112, Second Paragraph

Claims 64-84 have been rejected by the Patent Office under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Particularly, the Patent Office contends that claims 64-84 are indefinite because the claims are not clear as to whether "the antigen-adjuvant composition is water soluble, as recited in the claims of the ['758] patent. Furthermore, the Patent Office contends "it is not clear how an insoluble composition would be able to elicit an immune response." See Official Action, page 3, paragraph 3a.

Applicants respectfully traverse the Patent Office on this rejection. While a water-soluble embodiment is presently disclosed, neither the claims nor the specification require that the presently claimed antigen-adjuvant compositions be either water soluble or insoluble. Applicants respectfully submit that mere scope of a claim does not necessarily render the claim indefinite. Furthermore, it is recognized in the art that antigen-adjuvant compositions in general can be either water soluble or insoluble, depending on desired criteria. For example, particulate antigens can be potent immunogens, such as microspheres or virus-like particles (VLP). An insoluble composition can be formulated to become soluble or degrade once in the host to allow the induction of antigen-specific immune responses. It is also recognized in the art that the same antigen can elicit an antigen-specific response in both a soluble form (Marinero et al., Journal of Immunology 155:4621-4629, 1995; attached hereto as Exhibit A) and an insoluble form (VanCott et al., Journal of Immunology 156:1504-1514, 1996; attached hereto as Exhibit B).

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Summarily, applicants respectfully submit that claims 64-84 are in compliance with 35 U.S.C. § 112, second paragraph, based upon the arguments set forth above. Withdrawal of the rejection of claims 64-84 under 35 U.S.C. § 112, second paragraph, is therefore respectfully requested.

Claim Rejection - 35 U.S.C. § 102

Claims 64-84 have been provisionally rejected by the Patent Office under 35 U.S.C. § 102 as being anticipated by Gao et al, Abraham et al. and Elson et al. The Patent Office contends that the term "water-soluble" was required in order to distinguish the claims of the '758 Patent over the above cited art during prosecution. As such, the Patent Office argues that the claims of present application must also include the limitation "water-soluble" in order to distinguish the pending claims over the same cited art.

Applicants respectfully traverse the Patent Office on this rejection. "A claim is anticipated only if each and every element in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The present claims recite a method of eliciting an immune response against an antigen in a vertebrate subject. The method comprises providing an antigen-adjuvant composition comprising the antigen and a cytokine adjuvant selected from the group consisting of IL-1 α , IL-12, IL-15, IL-18 and combinations thereof; and administering the composition intramucosally to the subject such that initial contact occurs in mucosal tissue of the subject, whereby an immune response is elicited. None of the cited prior art teaches each and every element of the claims. Specifically, none of the cited prior art teaches an antigen-adjuvant composition comprising the antigen and one or more of the listed cytokine adjuvants, namely IL-1 α , IL-12, IL-15, IL-18 and combinations thereof.

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Since none of the cited prior art teaches each and every element of any of the claims, applicants respectfully submit that maintaining a rejection under 35 U.S.C. § 102 of any of the pending claims 64-84 based on the cited art is improper. Withdrawal of the provisional rejection of claims 64-84 under 35 U.S.C. § 102, is therefore respectfully requested.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. **50-0426**.

Respectfully submitted,

JENKINS, WILSON & TAYLOR, P.A.

Date: 12/18/2003

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